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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,270

03/03/2004

Masaaki Nomura

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8940

23911 7590 10/18/2007  
CROWELL & MORING LLP  
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EXAMINER
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AHMED, HASAN SYED

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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10/18/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/791,270	NOMURA ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) 3-14, 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 16-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/26/04 and 8/25/05</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt is acknowledged of applicants': (a) IDS, which was filed on 26 July 2004; (b) supplemental IDS, which was filed on 25 August 2005; and (c) response to the restriction requirement, which was filed on 1 August 2007.

\* \* \* \* \*

### ***Election/Restrictions***

Applicant's election without traverse of Group II and claim 20 in the reply filed on 1 August 2007 is acknowledged.

Claims 3-14, 22, and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1 August 2007.

\* \* \* \* \*

### ***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (b) as follows: Applicant failed to provide an English translation of the foreign applications JP 2004-022624 and JP 2004-057099. As such, the priority date of the instant application is interpreted as 3 March 2004, which is the filing date of 10/791,270.

\* \* \* \* \*

***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 03/037379 ("Hasenzahl").

Hasenzahl discloses a pharmaceutical composition comprising:

- the hard capsule of instant claim 1 (see page 12, line 27);
- the inorganic substance of claim 1 (see page 4, line 18); and
- the compound (faropenem) of claim 16 (see page 14, line 21).

\* \* \* \* \*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 03/037379 ("Hasenzahl").

Hasenzahl discloses a pharmaceutical composition (see above).

Hasenzahl explains that the disclosed composition is beneficial because it leads to, "...an improvement in the bioavailability of sparingly soluble medicaments..." See page 2, lines 21-22.

The Hasenzahl reference does not explicitly teach the compound of instant claim 17. Rather, it teaches the compound of instant claim 16 (see page 14, line 21). Because both the compound of claim 16 and 17 are penem antibiotics, one of ordinary skill in the art would have been motivated to add either the compound of instant claim 16 or 17 to the instant composition. There is a reasonable expectation that the addition of either the compound of instant claim 16 or 17 to the instant composition would provide an effective antibiotic effect. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add either the compound of instant claim 16 or 17 to the instant composition.

While the Hasenzahl reference does not explicitly teach the percentages of instant claim 18 and 19, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a hard capsule comprising an inorganic substance and a penem antibiotic, as taught by Hasenzahl. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it leads to an improvement in the bioavailability of sparingly soluble medicaments, as explained by Hasenzahl.

\*

2. Claims 1, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 03/037379 ("Hasenzahl") in view of U.S. Application No. 2003/0124188 ("Burnside").

Hasenzahl discloses a pharmaceutical composition (see above).

The Hasenzahl reference differs from the instant application in that it does not disclose the formulation of instant claim 20. However, capsule formulations with mixtures of functionally coated active agent and active agent without a functional coating were well known in the art at the time the instant application was filed, as shown by Burnside (see paragraphs 0021-0023).

The Burnside reference does not explicitly teach the ratio of instant claim 21, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant ratio.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a hard capsule comprising an inorganic substance and a penem antibiotic, with a mixture of coated and non-coated penem antibiotic, as taught by Hasenzahl in view of Burnside. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it leads to an improvement in the bioavailability of sparingly soluble medicaments, as explained by Hasenzahl.

☆

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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HUMERA N. SHEIKH  
PRIMARY EXAMINER